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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/944,862 | 08/31/2001 | Kevin P. Baker | P2548PIC12 | 4824 |

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| EXAMINER |
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LOEB, BRONWEN

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| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 02/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,862

Applicant(s)

BAKER ET AL.

Examiner

Bronwen M. Loeb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2001 and 05 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28, 29 and 32 is/are allowed.
- 6) ☒ Claim(s) 22-27, 30, 31, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: information regarding Copy of Papers Originally Filed.

DETAILED ACTION

This action is in response to the preliminary amendments filed 31 August 2001 and 5 September 2002. The 31 August 2001 amendment cancelled claims 1-21 and provided new claims 22-34. The 5 September 2002 amendment amended to related applications section of the specification.

Claims 22-34 are pending.

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § (120 or 119(e)) as follows:

The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. §112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

Upon review of the specification of the parent (or provisional) application and comparison with the specification of the present application, it is determined that the specification of parent (or provisional) application 09/254,311 (the national stage application of PCT/US98/25108) is not enabling for the use of the instantly claimed invention. PCT/US99/28301 (published as WO 00/32776) is the first parent that

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discloses the activity of inhibiting proliferation of stimulated T-lymphocytes. The specification of the 09/254,311 parent (or provisional) application does not teach or suggest an enabled use for the claimed polypeptides. The specification of '311 teaches PRO361 is possibly a mucin or a chitinase, however any use based on these speculations is not enabled. Since PRO361's activity of inhibiting proliferation of stimulated T-lymphocytes is not disclosed in the parent (or provisional) application and cannot be predicted from the teachings of the parent (or provisional) application, the parent (or provisional) application is not enabling for the instantly claimed invention. Thus, the requirements of the first paragraph of 35 U.S.C. §112 have not been met. Accordingly, claims 22-41 are assigned an effective filing date of 1 December 1999.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 22-27, 30, 31, 33 and 34 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a polypeptide having at least 80% sequence identity to the polypeptide of SEQ ID No. 83 or to the polypeptide lacking the signal peptide which polypeptide inhibits proliferation of stimulated T-lymphocytes, does not reasonably provide enablement for nucleic acids which encode a polypeptide having at least 80% sequence identity to SEQ ID No. 83 that do not have this activity. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification identifies PRO361 as a polypeptide having homology to mucin and/or chitinase proteins (p. 109, lines 31-33) as well as having sequences typical of the arginase family of proteins (p. 109, lines 27-29). The specification however does not disclose if PRO361 actually is a mucin and/or a chitinase nor does it teach any use with respect to these possible identities. The only biological activity demonstrated is inhibition of proliferation of stimulated T-lymphocytes (p. 141, Example 34). It is unknown if the extracellular domain alone (which the Examiner assumes is about 26-383, based on Figure 32) would possess this biological activity. While one of skill in the art would be able, without undue experimentation, to use polypeptides with this biological activity, neither the specification nor the prior art adequately teaches how to use PRO361 derivatives without this biological activity.

In conclusion, based on the broad nature of the claims, the lack of sufficient guidance in the prior art or the specification, and the large quantity of experimentation required to find a use for polypeptides with unknown biological activity, it is concluded that enablement is limited to those nucleic acids encoding structural variants which inhibit proliferation of stimulated T-lymphocytes.

4. Claims 22-26, 33 and 34 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as

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to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

This rejection is based on the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, first paragraph "Written Description" Requirement published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). The claims are drawn to 1) a polypeptide having at least 80%, 85%, 90%, 95% or 99% sequence identity to the polypeptide of SEQ ID No. 83, 2) a polypeptide having at least 80%, 85%, 90%, 95% or 99% sequence identity to the a polypeptide of SEQ ID No. 83 lacking the signal peptide, 3 and 4) a polypeptide having at least 80%, 85%, 90%, 95% or 99% sequence identity to the a polypeptide of SEQ ID No. 83 encoding the extracellular domain with or without the signal peptide, 5) the polypeptide of SEQ ID

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No. 83 and 6) the polypeptide encoded by the nucleotide sequence of the cDNA in ATCC Accession number 209621. The claims do not recite that the polypeptide possess any particular function, nor any particular conserved structure, or any other disclosed distinguishing feature. Thus the claims are drawn to a genus of polypeptides that is defined only by sequence identity.

The specification mentions the polypeptide of SEQ ID No. 83 that has the activity of inhibiting proliferation of stimulated T-lymphocytes. This disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all of the isolated nucleic acids based on the teachings in the specification. The specification does not teach any correlation between any sequence and the biological activity of inhibiting proliferation of T-cell lymphocytes. There is no disclosure of the amino acids in the hydrophobic core of the protein essential to proper folding. Therefore, the specification does not describe the claimed the isolated polypeptides in such full, clear, concise and exact terms so as to indicate that Applicant has possession of these isolated polypeptides at the time of filing the present application. Thus, the written description requirement has not been satisfied.

Conclusion

Claims 28, 29 and 32 are allowed. Claims 22-27, 30, 31, 33 and 34 are rejected.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

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(December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
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